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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/625,164	07/23/2003	Eddie Reed	2002(227497)	8006

7590 11/10/2009
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EXAMINER

HOEKSTRA, JEFFREY GERBEN

ART UNIT	PAPER NUMBER
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3736

MAIL DATE	DELIVERY MODE
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11/10/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/625,164	Applicant(s) REED ET AL.	
	Examiner JEFFREY G. HOEKSTRA	Art Unit 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 August 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 28-32,34-38 and 42-47 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 28-32,34-38 and 42-47 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 August 2009 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Notice of Amendment

1. In response to the amendment filed on 08/24/2009, amendment(s) to the specification, amended claim(s) 36, 37, 42, and 43, new claim(s) 44-47, and cancelled claim(s) 27, 40, and 41 is/are acknowledged. The current objections and rejections is/are *withdrawn*. The following new and/or reiterated grounds of rejection are set forth:

Drawings

2. Although the Examiner appreciates the increased clarity of the Drawings comprising photocopies received on 08/24/2009, these drawings are unacceptable.

3. The drawings are objected to because they (a) appear to be informal photocopies of the invention which are not formal hand drawn illustrations of the claimed invention, (b) appear to be illegible and accompanied by dark and/or stray markings, and (c) they do not clearly illustrate at least the claimed limitations comprising *inter alia*: the collection element, the brush with bristles, and the inner tube, and/or the shield.

4. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet,

and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the examiner does not accept the changes, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

5. Color photographs and color drawings are not accepted unless a petition filed under 37 CFR 1.84(a)(2) is granted. Any such petition must be accompanied by the appropriate fee set forth in 37 CFR 1.17(h), three sets of color drawings or color photographs, as appropriate, and, unless already present, an amendment to include the following language as the first paragraph of the brief description of the drawings section of the specification:

The patent or application file contains at least one drawing executed in color. Copies of this patent or patent application publication with color drawing(s) will be provided by the Office upon request and payment of the necessary fee.

Color photographs will be accepted if the conditions for accepting color drawings and black and white photographs have been satisfied. See 37 CFR 1.84(b)(2).

Claim Objections

6. Claims 28-32, 34-38 and 42 are objected to because of the following informalities: the claims interchange the term "the vaginal specimen" and "the

specimen". It appears the positive recitations of "the specimen" should be amended to read "the vaginal specimen" or "said vaginal specimen" for consistency throughout the claims. Appropriate correction is required.

7. Claims 42 and 43 are objected to because of the following informalities: the positive recitations of "a brush attached to said inner tube with a longitudinal axis and bristles" should apparently read "a brush attached to said inner tube, having a longitudinal axis, and bristles", "a brush having a longitudinal axis, attached to said inner tube, and bristles", or the like, to avoid indefiniteness issues with respect to depending claims 35 and 44. Appropriate correction is required.

8. Claim 43 is objected to because of the following informalities: the positive recitation in line 3 of "(a)" should apparently be deleted since the "(b)" was deleted. Appropriate correction is required.

9. Claim 47 is objected to because of the following informalities: the positive recitation in line 2 of "the sample" should apparently read "the vaginal specimen" and/or may be indefinite for lacking antecedent basis. Appropriate correction is required.

Claim Rejections - 35 USC § 112

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claims 28-32, 34-38, and 42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

12. Independent claim 42, from which claims 28-32 and 34-38 depend, positively recites in the last two lines “detecting the presence of HPV in the specimen without requiring that the specimen contains *endothelial cells*”. Claim 42 also requires that the vaginal specimen contains *cervical epithelial cells* and few or no *endocervical cells*.

13. The scope of claim 42 is indeterminate with respect to what cells comprise the vaginal specimen, although the specimen contains cervical epithelial cells and few or no endocervical cells, the recitation of “*endothelial cells*” is indefinite with respect to what cells in the vaginal specimen serve as the basis for detecting the presence of HPV.

14. It is indeterminate and indefinite what the term “endothelial cells” comprises as it appears to be a fusion of the terms “*endocervical cells*” and “*cervical epithelial cells*”.

15. For the purposes of examination on the merits and consistent with the instant disclosure and the interview summary mailed 07/30/2009, the claim is being treated as positively reciting “detecting the presence of HPV in the vaginal specimen without requiring that the vaginal specimen contains *endocervical cells*”.

Claim Rejections - 35 USC § 102

16. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

17. Claims 34-38 and 42-47 are rejected under 35 U.S.C. 102(e) as being anticipated by Wallach (US 2002/0120213 A1).

18. Wallach discloses a method for detecting human papilloma virus (HPV) in a self-collected vaginal specimen (abstract and paragraphs 1, 4, 5, 11-13, 21, and 30), said method comprising *inter alia*:

- obtaining the vaginal specimen (abstract and paragraphs 1, 4, 5, 11-13, 21, and 30) that contains cervical epithelial cells and few or no endocervical cells (abstract and paragraphs 1, 4, 5, 11-13, 21, and 30) (the Examiner notes Wallach is expressly concerned with gathering the cells from the epithelium layer of the cervix via self-collection by the patient, see paragraph 12) with a device (as best seen in Figure 2) comprising a collection element (15) (as best seen in Figures 1-2) (paragraphs 22-24 and 27-30) and a shield (20) (as best seen in Figure 2) (paragraphs 22-24 and 27-30) in a form an outer tube (20) (as best seen in Figure 2) (paragraphs 22-24 and 27-30) that surrounds said collection element (as best seen in Figure 2) (paragraphs 22-24 and 27-30),
- wherein said collection element comprises a retractable inner tube (14) (as best seen in Figures 1-2) (paragraphs 22-24 and 27-30) which is retractable with respect to said outer tube (paragraphs 28-29), and a brush (12) (as best seen in Figures 1-2) (paragraphs 22-24 and 27-30) attached to said inner tube (as best seen in Figures 1-2), having a longitudinal axis (the longitudinal axis along the length of the brush base as best seen in Figures 1-2), and having bristles (11) (as best seen in Figures 1-2) (paragraphs 22-24 and 27-30) that are substantially perpendicular to the brush longitudinal axis (as best seen in Figures 1-2),

- wherein the inner tube has a longitudinal axis (an axis orthogonal to the length of the handle 14 as best seen in Figures 1-2) and the inner tube longitudinal axis runs parallel to the brush longitudinal axis (as best seen in Figures 1-2),
- wherein the inner tube element and the outer tube element are cylindrical in shape (as best seen in Figure 2),
- wherein an inner tube length and an outer tube length are roughly (i.e. approximately) equal (as best seen in Figure 2)
- wherein the bristles comprise a flexible plastic material (paragraph 24) selected from a group consisting of: polyethylene, polyurethane, polyvinyl chloride, polysiloxanes, and nylon (paragraph 24), and
- wherein the device does not use an absorbent material to collect the vaginal specimen (as best seen in Figures 1-2) (paragraphs 22-24 and 27-30); and
- detecting the presence of HPV (abstract and paragraphs 1, 4, 5, 11-13, 21, and 30), including high risk HPV (abstract and paragraphs 1, 4, 5, 11-13, 21, and 30, especially paragraph 4), in the vaginal specimen through DNA testing (abstract and paragraphs 1, 4, 5, 11-13, 21, and 30) without requiring that the specimen contains endocervical cells (abstract and paragraphs 1, 4, 5, 11-13, 21, and 30) (the Examiner notes Wallach is expressly concerned with gathering the cells from the epithelium layer of the cervix via self-collection by the patient, see paragraph 12).

19. For clarity the Examiner notes with respect to “the longitudinal axis” of the brush and/or inner tube as claimed, “the longitudinal axis” is not required and/or defined to be

along a direction of insertion of the collection element into the patient or even along the length of the brush, inner tube, collection element, and/or device.

20. Furthermore the Examiner notes that the method disclosed by Wallach includes at least the following (although not claimed, Applicant discloses and/or is concerned with the following):

- the distal end of the shield is configured to assist in insertion of the device (paragraphs 11-12),
- the inner tube is covered by the shield during insertion into the patient (paragraphs 11-12),
- the shield and inner tube are moved relative to each other to enable cell sampling by the brush (paragraphs 11-12), and
- the brush and bristles thereon are moved within the patient to aid in the gathering of the cells from the epithelium layer of the cervix vaginal specimen sample cells (paragraphs 11-12).

Claim Rejections - 35 USC § 103

21. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

22. Claims 28-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wallach in view of Zavada et al (US 2003/0049828 A1, hereinafter Zavada).

23. Wallach discloses the claimed invention and is expressly concerned with the self collection of cervical epithelial cells for the detection, testing, and analysis of high grade HPV in the DNA of the cervical epithelial cells (paragraphs 4, 5, 11-13, and 30); however, Wallach appears silent with respect to the DNA testing specifics. Wallach discloses the claimed invention, as set forth and cited above, except for expressly disclosing the vaginal specimen testing including (a) extracting DNA and amplifying HPV nucleic acid to detect the presence of HPV and (b) contacting the vaginal specimen with a multiple polypeptides that bind to a HPV antibody or protein and subsequent detection of the bound antibody or protein in the vaginal specimen.

24. Zavada teaches DNA HPV specimen testing, comprising *inter alia*: (a) extracting DNA and amplifying HPV nucleic acid (paragraphs 33-34) to detect the presence of HPV and (b) contacting the vaginal specimen with a multiple polypeptides that bind to a HPV antibody (paragraph 35) or protein (paragraph 40) and subsequent detection of HPV (paragraph 17) in the vaginal specimen.

25. All of the biological sample collecting and biological sample diagnostic testing are known in Wallach and Zavada. The only difference is the combination of the biological sample collection and testing into a single invention. Thus, it would have been obvious to one having ordinary skill in the art at the time of the invention to combine the biological sample collecting and biological sample diagnostic testing as taught by Wallach with the biological sample diagnostic testing as taught by Zavada to achieve the predictable results of increasing the efficacy of a medical process to effectively and accurately diagnose HPV in a specimen by using well known diagnostic techniques.

Response to Arguments

26. Applicant's arguments with respect to claims 28-32, 34-38, and 42-47 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

27. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JEFFREY G. HOEKSTRA whose telephone number is (571)272-7232. The examiner can normally be reached on Monday through Friday 8am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571)272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Jeffrey G Hoekstra/
Examiner, Art Unit 3736

/Max Hindenburg/
Supervisory Patent Examiner, Art Unit 3736